

IN THE CLAIMS:

1. (Original) A hepatitis vaccine formulation comprising a bacteriophage particle the surface of which is unmodified and a pharmaceutically acceptable carrier therefor, the bacteriophage particle comprising an exogenous nucleic acid molecule encoding a hepatitis virus polypeptide which is capable of expression and presentation on the surface of an antigen presenting cell of an organism, such that an immune response to said polypeptide is raised in the organism.
2. (Original) The hepatitis vaccine according to Claim 1 for use in vaccinating against hepatitis types A, B, C, D, and/or E.
3. (Currently Amended) The hepatitis vaccine according to ~~either of claims 1 or 2~~ Claim 1 wherein the antigen expressed and presented on the surface of the antigen presenting cell is a hepatitis surface antigen.
4. (Currently Amended) The hepatitis vaccine according to ~~any preceding claim~~ Claim 2 wherein the bacteriophage has been engineered to express more than one hepatitis antigen.
5. (Original) A vaccine formulation comprising greater than 10^9 bacteriophage particles, the surface of each particle being unmodified, and a pharmaceutically acceptable carrier therefor, the bacteriophage particle comprising an exogenous nucleic acid molecule encoding a hepatitis virus polypeptide which is capable of expression and presentation on the surface of an antigen presenting cell of an organism, such that an immune response to said polypeptide is raised in the organism.

6. (Currently Amended) The vaccine formulation according to ~~any preceding claim~~ Claim 5 which is capable of eliciting a humoral and/or cellular immune response.

7. (Original) The vaccine formulation according to claim 5 for use in vaccinating against a virus, bacterium, fungus, yeast, protozoan, helminth, insect or transmissible spongiform encephalopathy.

8. (Original) The vaccine formulation according to claim 5 for use in eliciting an immune response against a cancer cell by means of the expression of a cancer cell specific antigen.

9. (Currently Amended) The vaccine formulation according to ~~any preceding claim~~ Claim 5 wherein the bacteriophage comprises transcriptional and/or translational regulators to facilitate expression of the polypeptide.

10. (Original) The vaccine formulation according to claim 9 comprising a eukaryotic promoter, such as the CMV, SV40, thymidine kinase or RSV promoter.

11. (Original) The vaccine formulation according to claim 9 which comprises the exogenous nucleic acid under control of a constitutive promoter and a controllable promoter.

12. (Currently Amended) The vaccine formulation according to ~~any preceding claim~~, Claim 9 wherein the bacteriophage is lambda (λ), p1 phage, T phage, Mu, fd, M13 or a filamentous phage.

13. (Currently Amended) The vaccine formulation according to ~~any preceding claim~~, Claim 9 wherein the bacteriophage is capable of expressing single or multiple copies of a polypeptide or a plurality of polypeptides.

14. (Currently Amended) The vaccine formulation according to ~~any preceding claim~~, Claim 9 wherein the bacteriophage is abortive to lytic growth in the natural bacterial flora of the chosen mammalian host.

15. (Currently Amended) The vaccine formulation according to ~~any preceding claim~~, Claim 9 further comprising inhibitors of lysosomal/endosomal enzymic catabolism and/or nuclear localisation signals.

16. (Currently Amended) The vaccine formulation according to ~~any preceding claim~~, Claim 9 further comprising an amount of the polypeptide to be expressed by the bacteriophage.

17. (Currently Amended) The vaccine formulation according to ~~any preceding claim~~, Claim 9 wherein the bacteriophage has been modified to express the polypeptide on the surface of the phage particle.

18. (Currently Amended) The vaccine formulation according to ~~any preceding claim~~, Claim 9 wherein the exogenous nucleic acid also encodes a polypeptide capable of augmenting the immune response.

19. (Currently Amended) The vaccine formulation according to ~~any preceding claim~~, Claim 9 further comprising an adjuvant.

In re: March
Application Serial No. To be assigned
Filed: Concurrently herewith
Page 6

International Appl. No.: PCT/GB03/004267
International Filing Date: October 2, 2003

20. (Currently Amended) The vaccine formulation according to ~~any preceding claim~~, Claim 9 wherein the bacteriophage is associated with a vehicle.

21. (Currently Amended) The vaccine formulation according to ~~any preceding claim~~, Claim 9 for use in the prophylaxis and/or treatment of a disease in a human or animal.

22. (New) The hepatitis vaccine according to Claim 2 wherein the antigen expressed and presented on the surface of the antigen presenting cell is a hepatitis surface antigen.